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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,597	12/19/2000	Bruce J. Barclay	VASC 1020-1	3762

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/15/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/740,597

Applicant(s)

BARCLAY ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-38 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-36 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-943)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Applicant's acknowledgement of the election of Species III for the stent and Species A for the covering in Paper No. 9 is noted. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Response to Amendment

The declaration under 37 CFR 1.132 filed 1/27/03 is insufficient to overcome the rejection of claims 28-36,38 based upon Ragheb as set forth in the last Office action because: the Examiner is not relying on the Ragheb reference for the polymer or drug positioning, but only for some teachings in the art. Applicant's declaration is moot in view of the new rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 28,29,31,32,34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski et al. (WO 97/40755) in view of Kropf (4760849) and Eury et al. (5605696). Zukowski et al. disclose (Figs. 15,16) a stent having a coiled body **501** with a porous graft material extending along and completely covering the coiled body. Zukowski also discloses the stent body is made of

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metal, page 9, col. lines 25,26. Zukowski additionally discloses the graft material is ePTFE and can also have a protective layer, page 9, lines 23,24,34,35. However, Zukowski et al. do not disclose a stent body that has spaced-apart parallel side elements joined by connector elements or a NO generator in the porous graft material. Kropf teaches a stent body with spaced-apart parallel side elements joined by connector elements, Fig. 5. Eury et al. teach a method of incorporating therapeutic materials into polymers that cover a stent, col. 1, lines 54-58. Eury also teaches that the drug can be a NO generator such as nitoprusside, col. 4, line 9. Eury additionally teaches a rate controlling membrane or means to delay migration of the drug can be used, col. 5, lines 18-20. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the device of Zukowski et al. in order to provide a stent with greater coverage area and to incorporate a drug such as a NO generator in the polymer as taught by Eury with the stent graft of Zukowski as modified by Kropf in order to locally administer a drug.

Claims 30,33, 35,36,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski (WO 97/40755) in view of Kropf '849 and Eury '696 as applied to claims 28 and 34 above, and further in view of Ragheb et al. ('904). Zukowski as modified by Kropf and Eury is explained supra. However, Zukowski in view of Kropf and Eury do not disclose the metal for the stent as nickel-titanium or to microencapsulate the drug and to use multiple drugs with the stent or a biodegradable polymer. Ragheb teaches the stent can be made from metal, such as nickel-titanium, col. 3, lines 58-59. Ragheb also discloses that drugs

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used on stents can be microencapsulated, col. 19, lines 60-63. Ragheb additionally discloses the stent can comprise an additional drug, col. 14, lines 53-54. The outer porous layer can be a polymer that is biodegradable, col. 13, lines 33-44. Drugs that can be delivered via the stent include taxol and heparin, col. 11, lines 1-11, 63-65. It would have been obvious to one of ordinary skill in the art to use Nitinol, an additional drug and a biodegradable polymer with the stent graft of Zukowski as modified by Kropf and Eury in order to enable the stent graft to provide a multiple treatment effects to the patient.

Response to Arguments

Applicant's arguments with respect to claim 28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738

April 10, 2003



Bruce Snow

Primary Examiner

